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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/006,627	01/13/1998	NICOLA GAIL WALLIS	GM10127	3981

25308 7590 11/17/2004

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EXAMINER	
MONSHIPOURI, MARYAM	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/17/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/006,627	Applicant(s) WALLIS ET AL.	
	Examiner Maryam Monshipouri	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *44-47* is/are allowed.

6)☒ Claim(s) *25-43 and 48-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: attachment

Claims 25-58 are under examination on the merits. Claims 1-24 are canceled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-43 and 57-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:1 and 3, does not reasonably provide enablement for any of the following:

(a) Isolated polynucleotide segment comprising a DNA sequence identical to SEQ ID NO:1, except that, over the entire length of said sequence up to 3 or 5 nucleotides are mutated **with no function** (see claims 25, 30).

(b) isolated polynucleotides comprising a DNA sequence that hybridizes to SEQ ID NO:1, under hybridization conditions recited in claim 34 **with no function** (see claim 34).

(c) isolated polynucleotides comprising a DNA sequence that encodes SEQ ID NO:2 except that, over the entire length of said sequence up to 3 or 5 nucleotides are mutated **with no function** (claim 37).

(d) isolated polynucleotides comprising a portion of at least 30-50 contiguous bases of SEQ ID NO:1 (claims 57-58) **with no function.**

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples,

4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification fails to teach the structural requirements of any of the polynucleotide homologs and fragments recited above (see parts a-d). In other words the skilled artisan does not know which critical residues in the above mentioned homologs must remain intact such that said homologs retain the capability of encoding histidine kinase. No examples of such residues are taught either. Current state of prior art indicates that any homolog of a polynucleotide sequence capable of encoding a full-length polypeptide is not necessarily going to encode said full-length polypeptide.

Therefore, due to lack of sufficient teachings and examples provided in the specification and due to unpredictability of prior art as to which residues in above mentioned homologs must be retained in order to encode products with kinase function the skilled artisan has to go through the burden of undue experimentation in order to screen for those homologs and fragments that are within the scope of this invention and as such the claims are not enabled.

Claims 26-29, 31-33, 35-36, 38-43 are rejected merely for depending from rejected base claims recited above.

Claims 25-43 and 57-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 25, 30, 34, 37 and 57-58 are

each directed to the following **genus** of polynucleotides that have not been adequately described in the specification.

(a) a genus of isolated polynucleotide segments comprising a DNA sequence identical to SEQ ID NO:1, except that, over the entire length of said sequence up to 3 or 5 nucleotides are mutated **with no function** (see claims 25, 30).

(b) a **genus** of isolated polynucleotides comprising a DNA sequence that hybridizes to SEQ ID NO:1, under hybridization conditions recited in claim 34 **with no function** (see claim 34).

(c) a **genus** of isolated polynucleotides comprising a DNA sequence that encodes SEQ ID NO:2 except that, over the entire length of said sequence up to 3 or 5 nucleotides are mutated **with no function** (claim 37).

(d) a **genus** of isolated polynucleotides comprising a portion of at least 30-50 contiguous bases of SEQ ID NO:1 (claims 57-58) **with/without function**.

The specification does not contain any disclosure of the function of all DNA sequences that are recited in sections (a-b) above. The genus of cDNAs that comprise each of the above cDNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a **single species** (i.e. SEQ ID NO:1 or 3) of each claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot

reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is reminded that in the case of section (d) the claimed polynucleotides are further subject to lack of written description rejection due to scarcity of structural information. This is because a sequence comprising mere 30 or 50 contiguous bases of a DNA capable of encoding a full-length polypeptide is generally incapable of encoding any products with similar function with said polypeptide. Thus, some additional structural information with regards to claimed portions are required in order to be able to construct DNA fragments that are within the scope of this invention, and said information is currently lacking in the specification.

Claims 26-29, 31-33, 35-36, 38-43 are rejected merely for depending from rejected base claims recited above.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 48-56 are rejected under 35 U.S.C. 102(a) as being anticipated by Wallis et al. (WO 97/23506, Jul 1997). Wallis teaches and claims an isolated polynucleotide (see its SEQ ID NO:1 in the attached sequence alignment) comprising a DNA sequence encoding SEQ ID NO:4 of this invention, anticipating claims 48 and 53. Its polynucleotide sequence comprises a sequence identical to SEQ ID NO:3 of this invention, anticipating claim 51. In claims 7-9, Wallis claims vectors and host cells comprising SEQ ID NO:3 of this invention, anticipating claims 49-50 and 54-55. In pages 29-30 Wallis teaches about methods of expressing its polynucleotides , anticipating claims 52 and 56 of this invention.

Claims 48-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Hodgson et al. (U.S. Patent No. 6,084,086, issued 7/2000).The applied reference has a common inventor (Wallis N.G.) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. Wallis teaches and claims a polynucleotide that has 100% identity to SEQ ID NO:3 of this invention, anticipating claims 48 and 53. Wallis also claims vectors and host cells comprising said sequence (see its claims 6-9) and methods of expressing said sequence, anticipating claims 49-52 and 54-56.

Claims 57-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Kunsch et al. (US20030054436A1, see also U.S. Patent No. 6737248). Kunsch teaches an isolated DNA sequence comprising at least 50 contiguous bases of SEQ ID NO:1, anticipating claims 57-58 of this invention (see the attached sequence alignment).

Allowable Subject Matter

Claims 44-47 are allowed. This is because an isolated polynucleotide comprising a DNA sequence encoding a polypeptide consisting of SEQ ID NO:2 is free of prior art. Further the prior art does not teach or suggest preparing such specifically claimed polynucleotide. Hence, said polynucleotide is also non-obvious. Since said polynucleotide is both novel and non-obvious, vectors and hosts comprising said polynucleotide and methods of expressing said polynucleotide are also novel and non-obvious as well.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Monshi

Maryam Monshipouri Ph.D.

Primary Examiner

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